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In The
Supreme Court of the United States

KATHLEEN SEBELIUS, ET AL.,
Petitioners,

v.

HOBBY LOBBY STORES, INC., ET AL.,
Respondents.

CONESTOGA WOOD SPECIALTIES CORPORATION, ET AL.,
Petitioners,

v.

KATHLEEN SEBELIUS, ET AL.,
Respondents.

On Writs Of Certiorari To The United States Courts Of Appeals For The Third And Tenth Circuits

AMICUS CURIAE BRIEF OF DRURY DEVELOPMENT CORPORATION, DRURY SOUTHWEST, INC., AND DRURY HOTELS COMPANY, LLC, WITH THE AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, CHRISTIAN MEDICAL ASSOCIATION, PHYSICIANS FOR LIFE, NATIONAL ASSOCIATION OF PRO LIFE NURSES, THE NATIONAL CATHOLIC BIOETHICS CENTER, AND NATIONAL ASSOCIATION OF CATHOLIC NURSES IN SUPPORT OF HOBBY LOBBY, ET AL. AND CONESTOGA WOOD SPECIALTIES, ET AL.

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

It is undisputed that a new, distinct human organism comes into existence during the process of fertilization. Many drugs and devices labeled by the U.S. Food and Drug Administration as "contraception," however, have post-fertilization mechanisms of action – which means that these drugs and devices work after a new human organism is created (at fertilization) but before implantation. While such contraceptive methods may prevent implantation and therefore "pregnancy," as defined by the Government[2] and its *amici*, these drugs and devices can also end the life of a new human organism.

Amici Curiae – which include for-profit companies as well as national healthcare non-profit organizations, described below – are sensitive to healthcare disparities and support a variety of public and private efforts that address health care affordability and accessibility. *Amici* oppose, however, the Government's

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[1] Pursuant to this Court's Rule 37.3(a), *Amici* have consent to file this brief. Conestoga et al. and the Government Defendants have filed blanket consent with this court; Hobby Lobby et al. has granted consent by letter, filed with this brief. Pursuant to this Court's Rule 37.6, *Amici* state that no counsel for any party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of the brief.

[2] For purposes of clarity in this brief, the private, non-governmental parties in these cases are referred to as "family businesses" and the governmental parties are referred to as "Government" or "Defendants."

mandate imposed on nearly all private insurance plans to cover drugs and devices with post-fertilization (*i.e.*, life-ending) mechanisms of action. This mandate violates the genuine and sincerely held religious beliefs and freedom of conscience of the plaintiff family businesses. Based on the destructive, post-fertilization effect of "emergency contraceptives" and the coercive, unconstitutional actions of the Government to compel the family businesses to pay for those drugs and devices with post-fertilization (*i.e.*, life-ending) mechanisms of action, *Amici* urge this Court to affirm the decision of the United States Court of Appeals for the Tenth Circuit and reverse the decision of the United States Court of Appeals for the Third Circuit Court.

Drury *Amici*

Drury Development Corporation, Drury Southwest, Inc., and Drury Hotels Company, LLC [collectively referred to herein as "Drury *Amici*"] are for-profit companies that collectively employ hundreds of individuals. Drury *Amici* and their affiliates own and operate, among other things, hotels, office buildings, strip shopping centers, billboard companies, and convenience gasoline stations. Eligible employees of Drury *Amici* participate in a self-funded health and welfare benefit plan administered by Drury Hotels Company, LLC. Currently, 3,710 employees are eligible to participate, and 2,302 have elected to participate.

Members of the Charles L. Drury, Sr., and the Robert A. Drury families [collectively referred to as "Drury Family"] who own/control Drury *Amici* are adherents of the Catholic faith and wish to conduct their business in a manner that does not violate the principles of their faith. Specifically, they believe that life is a sacred gift from God and that they are not permitted to cause or pay for the direct, intentional termination of human life. Drury *Amici* always have been operated in a manner consistent with this belief. Previous health plan policies provided by Drury *Amici* to their employees have excluded contraception, including "emergency contraception," from employee health plans.

Under the Affordable Care Act, Drury *Amici* must provide coverage for "preventive care" for women, which the Government has defined to include "emergency contraception." The employee health plans provided by Drury *Amici* are not grandfathered or otherwise exempt[3] from this mandate. Thus, with the plan renewal of January 1, 2013, Drury *Amici* were forced to choose between conducting business in a manner consistent with the religious principles of the members of the Drury Family or paying ruinous

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[3] Drury *Amici* do not qualify for the "religious employer" exemption and are not composed of non-profit entities (*i.e.*, Drury *Amici* cannot take advantage of the "temporary safe-harbor" set forth by the Government at 77 Fed. Reg. 8725 (Feb. 15, 2012)).

fines and penalties.[4] Coerced by the Government to make this unconstitutional decision, Drury *Amici* have been forced to violate the religious tenets of members of the Drury Family which Drury *Amici* have always followed and provide coverage of life-ending "emergency contraception" through their employee health plans.

Medical Organization *Amici*

The remaining *Amici* are six national medical organizations whose members include physicians, bioethicists, and other healthcare professionals who have a profound interest in protecting human life in their roles as healthcare providers and medical experts [collectively referred to herein as "Medical Organization *Amici*"]. As experts in the medical field, Medical Organization *Amici* provide documentation that a new human organism undisputedly begins at fertilization, and that "emergency contraception" has post-fertilization mechanisms of action.

Medical Organization *Amici* include the following:

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[4] Such fines would indeed be ruinous. Non-exempt employers who fail to provide certain services are subject to an assessment of $100 a day per employee, as well as potential of private enforcement suits. Drury *Amici*, with 3,710 eligible employees, would therefore face a penalty of up to $371,000 per day if it did not provide coverage of "emergency contraception." Drury *Amici* would also be subject to an annual fine of approximately $2,000 per full-time employee (not counting the first 30 employees).

American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG) is a non-profit professional medical organization consisting of 2,500 obstetrician-gynecologist members and associates. AAPLOG held the title of "special interest group" within the American College of Obstetricians & Gynecologists (ACOG) for 40 years, from 1973 until 2013, until ACOG discontinued the designation of "special interest group." AAPLOG is concerned about the potential long-term adverse consequences of abortion on a woman's future health and continues to explore data from around the world regarding abortion-associated complications in order to provide a realistic assessment and appreciation of abortion-related health risks for women.

Christian Medical Association, founded in 1931, is a non-profit national organization of Christian physicians and allied healthcare professionals with almost 16,000 members. It also has associate members from a number of allied health professions, including nurses and physician assistants. Christian Medical Association provides up-to-date information on the legislative, ethical, and medical aspects of abortion and its impact on maternal health.

Physicians for Life is a national non-profit medical organization that exists to draw attention to the issues of abortion and contraception. Physicians for Life encourages physicians to educate their patients not only regarding the innate value of human life at all stages of development, but also on the risks inherent in abortion.

National Association of Pro Life Nurses (NAPN) is a national non-profit nurses' organization with members in every state. NAPN unites nurses who seek excellence in nurturing for all, including mothers and the unborn. NAPN seeks to establish and protect ethical values of the nursing profession.

The National Catholic Bioethics Center, established in 1972, conducts research, consults, publishes, and educates to promote human dignity in health care and the life sciences, and derives its message directly from the teachings of the Catholic Church.

National Association of Catholic Nurses is a national non-profit organization that gives nurses of different backgrounds the opportunity to promote moral principles within the Catholic context in nursing and stimulate desire for professional development. The organization focuses on educational programs, spiritual nourishment, patient advocacy, and integration of faith and health.

SUMMARY OF ARGUMENT

The Affordable Care Act (ACA) requires that all private insurance plans "provide coverage for and shall not impose any cost sharing requirements for . . . preventive care and screenings [for women]."[5] The

[5] 42 U.S.C. § 300gg-13.

Government's[6] regulatory mandate implementing this provision (the "Mandate") requires that nearly all private health insurance plans fully cover, without co-pay, all drugs and devices labeled by the Food and Drug Administration (FDA) as "contraception."[7]

It is scientifically undisputed that a new human organism begins at fertilization. *See* Part I, *infra*. However, the FDA's definition of "contraception" is broad and includes drugs and devices with known post-fertilization (*i.e.*, life-ending) mechanisms of action.[8] *See* Part II, *infra*. As such, forcing employers to provide coverage of such life-ending drugs violates the conscientious beliefs of the family businesses and Americans across the nation.

The Government and its *amici* ignore the family businesses' documented objections to the post-fertilization effect (*i.e.*, life-ending effect) of such drugs, instead inserting disingenuous semantic arguments about when "pregnancy" begins. "Pregnancy" is not

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[6] For purposes of clarity in this brief, the private, non-governmental parties in these cases are referred to as "family businesses" and the governmental parties are referred to as "Government" or "Defendants."

[7] *See* Health Resources and Services Administration, *Women's Preventive Services: Required Health Plan Coverage Guidelines* (Aug. 1, 2011), http://www.hrsa.gov/womensguidelines/. All internet sites last visited January 3, 2014.

[8] *See* Food and Drug Administration, *Birth Control Guide* (Aug. 2012), http://www.co.burke.nc.us/vertical/sites/%7BDF44FA7A-21E3-466A-A30D-00122906F160%7D/uploads/FDA_Birth_Control_Guide-_Updated_August_2012.pdf.

the scientific benchmark; fertilization, which is the beginning of a new human organism, is the true scientific benchmark at issue here. When the post-fertilization mechanisms of action of "emergency contraceptives" are understood as ending the life of a developing human organism, it is clear that forcing the family businesses to pay for such drugs violates their rights and contradicts this nation's long-standing commitment to the freedom of conscience. *See* Part III, *infra*.

ARGUMENT

I. It is Undisputed that a New Human Organism is Created at Fertilization.

It is undisputed that a new, distinct human organism comes into existence during the process of fertilization.[9] Scientific literature states the following:

- "The fusion of sperm and egg membranes ***initiates the life*** of a sexually reproducing organism."[10]

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[9] *See, e.g.*, Condic, *When Does Human Life Begin? A Scientific Perspective* (The Westchester Institute for Ethics & the Human Person Oct. 2008), http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf; George & Tollefsen, EMBRYO 39 (2008).

[10] Marsden et al., *Model systems for membrane fusion*, CHEM. SOC. REV. 40(3):1572 (Mar. 2011) (emphasis added).

- "The ***life cycle of mammals begins*** when a sperm enters an egg."[11]
- "Fertilization is the process by which male and female haploid gametes (sperm and egg) unite to produce ***a genetically distinct individual***."[12]
- "The oviduct or Fallopian tube is the anatomical region where ***every new life begins*** in mammalian species. After a long journey, the spermatozoa meet the oocyte in the specific site of the oviduct named ampulla, and fertilization takes place."[13]
- "Fertilization – ***the fusion of gametes to produce a new organism*** – is the culmination of a multitude of intricately regulated cellular processes."[14]

The Government's own definition attests to the fact that life begins at fertilization. According to the National Institutes of Health, "fertilization" is the "process of union" of two gametes (*i.e.*, ovum and

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[11] Okada et al., *A role for the elongator complex in zygotic paternal genome demethylation*, NATURE 463:554 (Jan. 28, 2010) (emphasis added).

[12] Signorelli et al., *Kinases, phosphatases and proteases during sperm capacitation*, CELL TISSUE RES. 349(3):765 (Mar. 20, 2012) (emphasis added).

[13] Coy et al., *Roles of the oviduct in mammalian fertilization*, REPRODUCTION 144(6):649 (Oct. 1, 2012) (emphasis added).

[14] Marcello et al., *Fertilization*, ADV. EXP. BIOL. 757:321 (2013) (emphasis added).

sperm) "whereby the somatic chromosome number is restored *and the development of a* ***new individual*** *is initiated*."[15] Thus, in the context of human life, a new individual human organism is initiated at the union of ovum and sperm.

One textbook similarly explains the following:

> Human development begins at fertilization when a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to produce a single cell – a zygote. This highly specialized, totipotent cell marked ***the beginning of each of us as a unique individual***.[16]

Thus, a new human organism is created *before* the developing embryo implants in the uterus – *i.e.*, before that time at which some people consider a woman "pregnant."

The Government and its *amici* have at times tried to blur this distinct line with semantics about when "pregnancy" begins. Relying on a definition of pregnancy that begins at "implantation," the Government and its *amici* argue that "emergency contraceptives" are not "abortifacients." However, this is a nonresponse to the concern that a drug or device can

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[15] National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2013), http://www.merriam-webster.com/medlineplus/fertilization (emphasis added).

[16] Moore & Persaud, THE DEVELOPING HUMAN 16 (7th ed. 2003) (emphasis added).

work after fertilization by blocking the implantation of a developing human embryo. Such drugs might not end a "pregnancy" under the Government's definition, but it does end the life of a unique human being. What the family businesses – and *Amici* – conscientiously oppose is not simply the ending of a "pregnancy," but the ending of human life itself.

II. Drugs and Devices Defined by the FDA as "Emergency Contraception" Have Post-Fertilization Mechanisms of Action.

Drugs and devices with post-fertilization (*i.e.*, life-ending) mechanisms of action are included in the FDA definition of "contraception." Even though these drugs and devices may end a developing, distinct human being's life by preventing implantation, they are labeled by the FDA as "contraception." However, referring to such drugs as "contraception" is deceiving in that the term implies to the public only the *prevention of fertilization*. Yet the scientific endpoint which defines a drug as a "contraceptive" is the ability to prevent a "pregnancy" – which in operational terms means preventing detection of a positive pregnancy test at the end of a woman's cycle, nearly ten days to two weeks after embryo formation.

Thus, because the FDA's criterion in categorizing a drug as "contraception" is whether a drug can work by preventing "*pregnancy*" – which the FDA defines as beginning at "implantation," not fertilization – drugs that interfere with *implantation*, which occurs

days *after* fertilization and the creation of a new human organism, are categorized as "contraception."[17]

There is no dispute among the parties that at least some of these drugs have post-fertilization (*i.e.*, life-ending) mechanisms of action and can prevent implantation of an already-developing human embryo. The Government has conceded before this Court that various "emergency contraceptives" can work after fertilization but before implantation. For example, the Government concedes that copper IUDs work "possibly by preventing implantation (of a fertilized egg in the uterus)"; likewise, the Government concedes that an IUD with progestin can work by "altering the endometrium." Brief of Government Respondents in *Sebelius v. Hobby Lobby Stores, Inc.*, at 9 n.4. Further, the Government concedes that Plan B "may inhibit implantation (of a fertilized egg in the uterus) by altering the endometrium," and that *ella* "may also work by altering the endometrium in a way that may affect implantation (of the fertilized egg in the uterus)." *Id.*

In *Hobby Lobby Stores, Inc. v. Sebelius*, the United States Court of Appeals for the Tenth Circuit noted the following:

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[17] For an overview of how the definition of "pregnancy" has changed, *see* Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of Conception and Pregnancy*, 9 NAT'L CATHOLIC BIOETHICS QUARTERLY 542 (2009).

> Both the government and the medical amici supporting the government concede that at least some of the contraceptive methods to which the plaintiffs object have the potential to prevent uterine implantation. . . . [W]e need not wade into scientific waters here, given the above-noted agreement that some of the challenged devices function in a manner that Hobby Lobby and Mardel find morally problematic.

723 F.3d 1114, 1123 n.3 (10th Cir. 2013). Unless the parties have requested that this Court review this conclusion of the Tenth Circuit – and they have not – the Tenth Circuit's conclusion stands. The Government and its *amici* are barred from arguing that the family businesses are mistaken in their belief that "emergency contraception" can work to end life after fertilization and before implantation.[18]

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[18] One *amicus* brief cited by the Tenth Circuit was filed by Physicians for Reproductive Health, American College of Obstetricians & Gynecologists, Dr. James Trussell, and other medical organizations or individuals, and a version of that brief is likely to be filed in this Court [collectively referred to herein as "Government's medical *amici*"]. The previous versions of that brief are filled with semantic arguments, such as when "pregnancy" begins and whether a drug can be considered an "abortifacient;" however, such semantic arguments miss the mark. When "pregnancy" begins is not the scientific benchmark at issue here. The relevant scientific benchmark is when the life of a human organism begins – and that is undisputedly at fertilization.

Previous versions of the brief filed by the Government's medical *amici* also argue that certain forms of "emergency

(Continued on following page)

Additional statements by the Government defendants and their *amici* further demonstrate that there is no dispute as to the post-fertilization mechanism of action of some "contraceptives." For example, when promoting the Mandate, Defendant Kathleen Sebelius, Secretary of Health and Human Services (HHS), admitted that the FDA's definition of "contraception" extends to *blocking the implantation* of an already developing human embryo: "The Food and Drug Administration has a category [of drugs] that prevent fertilization *and implantation*. That's really the scientific definition."[19] Defendant Sebelius stated that under the new Mandate, "[t]hese covered prescription drugs are specifically those that are

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contraception" do not prevent implantation – but these claims are purely speculative. The sources cited by the Government's medical *amici* never present conclusive scientific evidence that "emergency contraceptives" do not interfere with implantation. The Government's medical *amici* try to make up for this lack of evidence by claiming that the "emergency contraceptives" Plan B and *ella* work "***primarily***, ***if*** not exclusively, by inhibiting ovulation" or that "the ***primary***, and ***perhaps*** only, method of action" is pre-fertilization. But such statements are by no means scientifically conclusive. Just because Plan B and *ella* work "primarily" before fertilization does not mean that they do not also work after fertilization. Simply put, the Government's medical *amici* solely rely on semantics and speculation and skirt the scientific fact that a new life begins at fertilization.

[19] Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage "Historic" New Guidelines Cover Contraception, Not Abortion* (Aug. 2, 2011), http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771 (emphasis added).

designed to *prevent implantation.*"[20] The Government defendants know and admit that these drugs work after fertilization.

In his most recent study on "emergency contraception," Dr. James Trussell, who appeared as an *amicus* supporting the Government in both cases below, states: "To make an informed choice, women must know that [emergency contraception pills] . . . may at times inhibit implantation. . . ."[21] Although an advocate of "emergency contraception," Dr. Trussell believes that the scientific difference between a drug that prevents fertilization of an egg and one that may also prevent implantation of a unique human organism is significant enough that it must be disclosed to a potential user. He has also stated that these post-fertilization effects "should certainly be [acknowledged and] celebrated, because without them the [contraceptive] method would not provide as much benefit as they do."[22] In other words, if fertilization has occurred, the method provides "benefit" by preventing implantation.

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[20] *Id.* (emphasis added).

[21] Trussell et al., *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy* (Office of Population Research at Princeton University June 2010).

[22] Raymond et al., *Embracing post-fertilisation methods of family planning: a call to action*, J. FAM. PLAN. REPROD. HEALTH CARE (2013), http://press.psprings.co.uk/jfprhc/september/jfprhc100702.pdf.

Moreover, a new drug classified by the FDA as "emergency contraception" – Ulipristal Acetate (*ella*) – is actually an abortion-inducing drug, because it can kill a human embryo *after* implantation.

An understanding of these post-fertilization mechanisms of action, discussed below, further demonstrates that "emergency contraception" can end the life of an already developing human organism.

A. Plan B can prevent implantation.

In 1999, the FDA approved the distribution of the drug known as Plan B. Although called "emergency contraception," the FDA-approved labeling acknowledges that Plan B can prevent implantation of an already-developing human embryo.[23] Further, the FDA states on its website, "[i]f fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation)."[24] The same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step.[25] The Government relies on

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[23] Plan B Approved Labeling, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf.

[24] Food and Drug Administration, *FDA's Decision Regarding Plan B: Questions and Answers* (updated Apr. 30, 2009), http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm.

[25] Duramed Pharmaceuticals, *How does Plan B One-Step work?* (2010), http://www.planbonestep.com/faqs.aspx (explaining that Plan B can work "by preventing attachment (implantation) to the uterus (womb)").

the Plan B drug label when it similarly explains the mechanisms of action of Plan B in its *Hobby Lobby* brief. *See* Brief of Government Respondents in *Sebelius v. Hobby Lobby Stores, Inc.*, at 9 n.4.

Under the Government's Mandate, the family businesses are forced to pay for Plan B, despite its life-ending effect on already formed unique human organisms, in violation of the family businesses' genuinely held religious beliefs.

B. Ulipristal Acetate (*ella*) can prevent implantation or kill an implanted embryo.

In 2010, the FDA approved the drug Ulipristal Acetate (*ella*) as another "emergency contraceptive." Importantly, *ella* is not an "improved" version of Plan B; instead, the chemical make-up of *ella* is similar to the abortion drug RU-486 (brand name Mifeprex). Like RU-486, *ella* is a selective progesterone receptor modulator (SPRM) – "[t]he mechanism of action of ulipristal (*ella*) in human ovarian and endometrial tissue is identical to that of its parent compound mifepristone."[26] This means that though *labeled* as "contraception," *ella* works the same way as RU-486. By blocking progesterone – a hormone necessary to build and maintain the uterine wall

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[26] Harrison & Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health*, 45 ANNALS PHARMACOTHERAPY 115 (Jan. 2011).

during pregnancy – an SPRM can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by essentially starving him or her to death. Put another way, *ella can abort a pregnancy*, whether you define "pregnancy" as beginning at fertilization or at implantation.[27]

Studies confirm that *ella* is harmful to a human embryo.[28] The FDA-approved labeling – relied upon by the Government in its *Hobby Lobby* brief – notes that *ella* may "affect implantation"[29] and contraindicates use of *ella* in the case of known or suspected pregnancy. A study funded by *ella*'s manufacturer explains that SPRMs (drugs that block the hormone progesterone), "including ulipristal acetate," can "impair implantation."[30] While the study theorizes that the dosage used in its trial "might be too low to inhibit implantation,"[31] it states affirmatively that

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[27] *See* Gacek, *Conceiving Pregnancy*, *supra*.

[28] European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone* 16 (2009), http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf.

[29] *ella* Labeling Information (Aug. 13, 2010), http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

[30] Glasier et al., *Ulipristal acetate versus levongestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555 (Jan. 2010).

[31] In the Glasier study, "follow-up was done 5-7 days after expected menses. If menses had occurred and a pregnancy test was negative, participation [in the study] ended. If menses had not occurred, participants returned a week later." Considering

(Continued on following page)

"an additional postovulatory mechanism of action," *e.g.*, impairing implantation, "cannot be excluded."

Thus, *ella* has the potential to destroy a human embryo. Notably, at the FDA advisory panel meeting for *ella*, Dr. Scott Emerson, a professor of Biostatistics at the University of Washington and a panelist, raised the point that the low pregnancy rate for women who take *ella* four or five days after intercourse suggests that the drug *must* have an "abortifacient" quality.[32]

In short, *ella* goes beyond any other "contraceptive" approved by the FDA at the time of the Affordable Care Act's enactment. By approving *ella* as "contraception," the FDA removed, not simply blurred, the line between "contraception" and "abortion" drugs because *ella* can work by ending an established "pregnancy."

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that implantation must occur *before* menses, the study could not, and did not attempt to, measure an impact on an embryo prior to implantation or even shortly after implantation. *ella* was not given to anyone who was known to already be pregnant (upon enrollment participants were given a pregnancy test and pregnant women were excluded from the study). The only criterion for *ella* "working" was that a woman was not pregnant in the end. Whether that was achieved through blocking implantation or killing the embryo after implantation was not determinable.

[32] *See* Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs (June 17, 2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf.

Further, though "indicated" for contraceptive use, mandated coverage for *ella* opens the door to the funding (through health insurance) of purposeful, off-label abortion usage of the drug. Already, *ella* is available for sale online, where a purchaser need only fill out a questionnaire to obtain the drug, with no physician or pharmacist to examine the patient, explain the risks in person, or verify the identity and intentions of the purchaser.

Thus, contrary to their religious and conscientious beliefs, the family businesses are required to pay for *ella* – an abortion-inducing drug – under the Government's Mandate.

C. Intrauterine Devices (IUDs) can also prevent implantation.

Copper Intrauterine Devices (IUDs) are heavily promoted as another form of "emergency contraception." IUDs can block the implantation of a human embryo after fertilization.[33] In his study on "emergency contraceptives," Dr. Trussell concludes that "[i]ts very high effectiveness implies that emergency insertion of a copper IUD *must* be able to prevent

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[33] *See* Department of Health and Human Services, *Birth Control Methods* (Nov. 21, 2011), http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf ("If fertilization does occur, the IUD keeps the fertilized egg from implanting in the lining of the uterus.").

pregnancy *after fertilization.*"[34] Put another way, IUDs are so effective *because* they do not just prevent conception – they can kill an already developing human embryo.

Clearly, under the Government's Mandate, the family businesses are required to pay for devices that can kill human embryos, contrary to their religious and conscientious beliefs.

III. The Mandate Violates Sincerely Held Religious Beliefs and Freedom of Conscience.

The plaintiff family businesses are required under the Mandate to provide insurance coverage for drugs and devices with life-ending mechanisms of action, including "emergency contraception." The family businesses have made clear their conscientious objection to paying for such life-ending drugs, and if the family businesses do not comply with the Government's Mandate, they will face potentially ruinous penalties.[35] Clearly, the family businesses are being forced to choose between either following their religious and conscientious beliefs or complying with the law. It is exactly this type of coercive dichotomy that

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[34] *See* Trussell, *Emergency Contraception*, *supra* (emphasis added).

[35] *See* 26 U.S.C. § 4980H(a), (c)(1); 26 U.S.C. § 4980D(b); 29 U.S.C. § 1132(a)(1)(B); 42 U.S.C. § 300gg-22(b)(2)(C)(i). *See also* Cong. Research Serv., RL 7-5700 (Feb. 24, 2012).

violates the U.S. Constitution's guarantee of freedom of conscience.

Freedom of conscience is a fundamental right that has been respected and protected since the founding of our Nation. Since that time, the paramount importance of this historic right has been affirmed by our Founders, by the U.S. Supreme Court, and by Congress. In short, history, tradition, and jurisprudence affirm that a person cannot be forced to commit an act that is against his or her moral, religious, or conscientious beliefs – including payment for such an act – and this history, tradition, and jurisprudence unequivocally support the family businesses in these cases.

A. Freedom of Conscience is a fundamental right affirmed by our Founders.

The First Amendment guarantees that Congress shall make no law prohibiting the free exercise of religion. U.S. CONST. amend. I. At the very root of that promise is the guarantee that the government cannot force a person to commit an act in violation of his or her religion.[36]

The signers to the religion provisions of the First Amendment were united in a desire to protect the

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[36] *See generally* McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 HARV. L. REV. 1409 (1990).

"liberty of conscience." Having recently shed blood to throw off a government which dictated and controlled their religion and practices, guaranteeing freedom of conscience was of utmost importance.[37]

Thomas Jefferson made it clear that freedom of conscience is not to be subordinate to the government:

> [O]ur rulers can have authority over such natural rights only as we have submitted to them. The rights of conscience we never submitted, we could not submit. We are answerable for them to our God.[38]

Jefferson also stated that no provision in the Constitution "ought to be dearer to man than that which protects the rights of conscience against the enterprises of civil authority."[39]

Jefferson also maintained that forcing a person to *contribute* to – much like forcing the family businesses to pay for – a cause to which he or she abhorred was "tyrannical."[40] This belief formed the basis of Jefferson's bill in Virginia, which prohibited the

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[37] The Founders often used the terms "conscience" and "religion" synonymously. Berg, *Free Exercise of Religion*, in THE HERITAGE GUIDE TO THE CONSTITUTION 310 (2005). Thus, adoption of the "religion" clauses does not mean that the Founders were ignoring freedom of conscience. The two were inextricably intertwined.

[38] Jefferson, *Notes on Virginia* (1785).

[39] Jefferson, Letter to New London Methodists (1809).

[40] Boyd, THE PAPERS OF THOMAS JEFFERSON 545 (1950).

compelling of a man to furnish money for the propagation of opinions to which he was opposed.[41] Jefferson – who considered it "tyrannical" to force a person to contribute monetarily to a position he disagreed with – would likely be aghast at a law requiring payment for a drug that is conscientiously objectionable.

Likewise, James Madison, considered the Father of the Bill of Rights, was also deeply concerned that the freedom of conscience of Americans be protected. Madison stated:

> The Religion then of every man must be left to the conviction and conscience of every man; and it is the right of every man to exercise it as these may dictate. This right is in its nature *an unalienable right.*[42]

In fact, Madison described the conscience as "the most sacred of all property."[43] Madison also amended the Virginia Declaration of Rights to state that all

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[41] Thus, not only is Jefferson the author of the Declaration of Independence, but he is also the author of one of this Nation's first statutes granting the right to refuse to participate or to act because of conscientious convictions. Jefferson was so proud of this accomplishment that he had "Author of the . . . Statute of Virginia Religious Freedom. . . ." etched on his gravestone.

[42] Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15 (1785) (emphasis added).

[43] Milton, THE QUOTABLE FOUNDING FATHERS: A TREASURY OF 2,500 WISE AND WITTY QUOTATIONS 36-37 (2005).

men are entitled to full and free exercise of religion, "according to the dictates of conscience."

Madison understood that if man cannot be loyal to himself, to his conscience, then a government cannot expect him to be loyal to less compelling obligations, statutes, judicial orders, or professional duties. If the government demands that he betray his conscience, the government has eliminated the only moral basis for obeying any law. Madison considered it "the particular glory of this country, to have secured the rights of conscience which in other nations are least understood or most strangely violated."[44]

George Washington maintained that "the establishment of Civil and Religious Liberty was the Motive that induced me to the field of battle," and he advised Americans to "labor to keep alive in your breast that little spark of celestial fire called conscience."[45] Washington also maintained that the government should accommodate religious persons:

> The conscientious scruples of all men should be treated with great delicacy and tenderness: and it is my wish and desire, that the laws may always be extensively accommodated to them, as a due regard for

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[44] Madison, Speech Delivered in Congress (Dec. 22, 1790).

[45] Novak & Novak, WASHINGTON'S GOD 111 (2006); Milton, *supra*.

> the protection and essential interests of the nation may justify and permit.[46]

John Adams stated that "no subject shall be hurt, molested, or restrained, in his person, liberty, or estate, for worshipping God in the manner most agreeable to the dictates of his own conscience."[47] Patriot leader Samuel Adams wrote that the liberty of conscience is an original right.[48]

Forcing the family businesses to pay for drugs and devices which have the effect of ending human life and to which they are conscientiously opposed eviscerates the very purpose for which this Nation was founded and formed. As Thomas Jefferson charged us:

> [W]e are bound, you, I, every one, to make common cause, even with error itself, to maintain the common right of freedom of conscience. *We ought with one heart and one hand hew down the daring and dangerous efforts of those who would seduce the public*

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[46] Washington, Letter to the Religious Society Called Quakers (1789).

[47] Adams, *A Declaration of the Rights of the Inhabitants of the Commonwealth of Massachusetts*, in REPORT FROM COMMITTEE BEFORE THE CONVENTION OF DELEGATES (1779).

[48] Cushing, THE WRITINGS OF SAMUEL ADAMS 350-59 (vol. II, 1906).

opinion to substitute itself into . . . tyranny over religious faith. . . ."[49]

B. Freedom of Conscience is a fundamental right affirmed by the U.S. Supreme Court.

This Court has consistently ruled in favor of protecting the freedom of conscience of every American. "Freedom of conscience" is referenced explicitly throughout Supreme Court jurisprudence. *See, e.g., Baird v. State Bar of Ariz.*, 401 U.S. 1, 6 (1971) ("This conjunction of liberties is not peculiar to religious activity and institutions alone. The First Amendment gives freedom of mind the same security as freedom of conscience."); *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 506 n.2 (1969) (referencing "constitutionally protected freedom of conscience").

Further, this Court has held that laws cannot abridge expressions protected by the First Amendment simply because a corporation is the source of protected conduct. *See Citizens United v. Fed. Election Comm'n*, 558 U.S. 310 (2010); *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765 (1978).

This Court has stated that "*[f]reedom of conscience . . . cannot be restricted by law.*" *Cantwell v. Conn.*, 310 U.S. 296, 303 (1940) (emphasis added). While the "freedom to believe" is absolute, the

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[49] Jefferson, Letter to Edward Dowse, Esq. (Apr. 19, 1803) (emphasis added).

"freedom to act" is not; however, "in every case," regulations on the freedom to act cannot "unduly infringe the protected freedom." *Id.* at 303-04.

In the 1940s, this Court considered regulations requiring public school students to recite the pledge to the American flag, ultimately vindicating the students' freedom of conscience. Initially, however, the Court ruled against a group of Jehovah's Witnesses who sought to have their children exempted from reciting the pledge. *Minersville Sch. Dist. v. Gobitis*, 310 U.S. 586 (1940).[50] However, in just three short years, the Court reversed this decision. In *West Virginia State Board of Education v. Barnette*, the Court stated:

> If there is any fixed star in our constitutional constellation, it is that no official, high or

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[50] Even though *Gobitis* was ultimately decided incorrectly, Justice Frankfurter, writing the majority opinion, did expound upon the balance between the interest of the schools and the interest of the students. He saw that the claims of the parties must be reconciled so as to "prevent either from destroying the other." *Gobitis*, 310 U.S. at 594. Because the liberty of conscience is so fundamental, "every possible leeway" must be given to the claims of religious faith. *Id.* On the other hand, Justice Frankfurter stated, similarly to what the Government has argued here, that "[t]he mere possession of religious convictions which contradict the relevant concerns of a political society does not relieve the citizen from the discharge of political responsibilities." *Id.* at 594-95. However, such conclusions were ultimately overthrown in *Barnette*, and as such this Court should reject any similar arguments that "religious convictions which contradict the relevant concerns of a political society" must submit to an overreaching authority.

> petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein. . . . [L]ocal authorities [may not] transcend[ ] constitutional limitations on their power and invade[ ] the sphere of intellect and spirit which it is the purpose of the *First Amendment to our Constitution* to reserve from all official control.

Barnette, 319 U.S. 624, 642 (1943) (emphasis in original). The Court also stated, "[F]reedom to differ is not limited to things that do not matter much. . . . The test of its substance is the right to differ as to things that touch the heart of the existing order." *Id.*[51] Based upon these principles, the Court ruled it unconstitutional to force public school children to perform an act that was against their religious beliefs.

Barnette has been affirmed on numerous occasions, including in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), where the Court stated:

> It is conventional constitutional doctrine that where reasonable people disagree the

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[51] "The very purpose of a *Bill of Rights* was to withdraw certain subjects from the vicissitudes of political controversy, to place them beyond the reach of majorities and officials and to establish them as legal principles to be applied by the courts. One's . . . freedom of worship and assembly, and other fundamental rights may not be submitted to vote; they depend on the outcome of no elections." *Barnette*, 319 U.S. at 638 (emphasis in original).

> government can adopt one position or the other. *That theorem, however, assumes a state of affairs in which the choice does not intrude upon a protected liberty.* Thus, while some people might disagree about whether or not the flag should be saluted, or disagree about the proposition that it may not be defiled, *we have ruled that a State may not compel or enforce one view or the other.*

Id. at 851 (citing *Barnette*, 319 U.S. 624) (other citations omitted) (emphasis added).

In the context of an obligatory flag salute and pledge, the Court has established the principle that to force parents and children to choose between their religious beliefs and their public education is a clear violation of their First Amendment rights. Likewise, forcing the family businesses to choose between adhering to their religious, moral, or conscientious convictions and the potential of heavy fines – or going out of business altogether – and complying with the Mandate is an unconstitutional exercise of state power.

In the 1960s and 1970s, the Court continued to protect Americans' freedom of conscience. In a notable example, the Court protected men who were conscientiously opposed to war. Section 6(j) of the Universal Military Training and Service Act contained a conscience clause exempting men from the draft who were conscientiously opposed to military service

because of "religious training and belief."[52] In *United States v. Seeger* and *Welsh v. United States*, the Court extended draft exemptions to "all those whose consciences, spurred by deeply held moral, ethical, or religious beliefs, would give them no rest or peace if they allowed themselves to become part of an instrument of war." *Welsh*, 398 U.S. 333, 344 (1970) (affirming *Seeger*, 380 U.S. 163 (1965)).

Welsh acknowledged that § 6(j) protected persons with "intensely personal" convictions – even when other persons found those convictions "incomprehensible" or "incorrect." *Welsh*, 398 U.S. at 339. Seeger and Welsh "held deep conscientious scruples against taking part in wars where people were killed. Both strongly believed that killing in war was wrong, unethical, and immoral, and their consciences forbade them to take part in such an evil practice." *Id.* at 337. Important here is Welsh's statement:

> I believe that human life is valuable in and of itself; in its living; therefore I will not injure or kill another human being. . . . I cannot, therefore, conscientiously comply with the Government's insistence that I assume

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[52] Section 6(j) did not embody a "new" idea. Early colonial charters and state constitutions spoke of freedom of conscience as a right, and during the Revolutionary War, many states granted exemptions from conscription to Quakers, Mennonites, and others with religious beliefs against war.

> duties which I feel are immoral and totally repugnant.

Id. at 343.

The holdings in these two cases demonstrate a strong commitment by this Court to protect freedom of conscience. Like Welsh, the family businesses believe that human life is valuable – at all stages and in all situations. As discussed *supra*, "emergency contraception" has the potential to kill developing human embryos. Being forced to pay for the termination of a human life is just as objectionable as being forced to participate in the termination of human life in war. Indeed, paying for the act *is* participating in the act.

C. Freedom of Conscience is a fundamental right affirmed by Congress.

Congress likewise has considered and passed numerous measures expressing the federal government's commitment to protecting the freedom of conscience.

Congress addressed the issue of conscience just weeks after the Supreme Court decided *Roe v. Wade*. In 1973, Congress passed the first of the Church Amendments.[43] The original and subsequent Church Amendments protect healthcare providers from discrimination by recipients of U.S. Department of

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[43] 42 U.S.C. § 300-7.

Health and Human Services (HHS) funds on the basis of their objection, because of religious belief or moral conviction, to performing or participating in *any* lawful health service or research activity.

In 1996, § 245 of the Public Health Service Act, known as the Coats Amendment, was enacted to prohibit the federal government and state or local governments that receive federal financial assistance from discriminating against individual and institutional healthcare providers, including participants in medical training programs, who refused to, among other things, receive training in abortions; require or provide such training; perform abortions; or provide referrals or make arrangements for such training or abortions.[54] The measure was prompted by a 1995 proposal from the Accreditation Council for Graduate Medical Education to mandate abortion training in all obstetrics and gynecology residency programs.

The most recent federal conscience protection, the Hyde-Weldon Amendment, was first enacted in 2005 and provides that no federal, state, or local government agency or program that receives funds under the Labor, Health and Human Services (LHHS) appropriations bill may discriminate against a healthcare provider because the provider refuses to provide, pay for, provide coverage of, or refer

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[54] 42 U.S.C. § 238n.

for abortion.[55] The Amendment is subject to annual renewal and has survived multiple legal challenges.[56]

Congress has also acted to provide specific conscience protections in the provision of contraceptives. For example, in 2000, Congress passed a law requiring the District of Columbia to include a conscience clause protecting religious beliefs and moral convictions in any contraceptive mandate.[57] Similarly, in 1999, Congress prohibited health plans participating in the federal employees' benefits program from discriminating against individuals who refuse to prescribe contraceptives.[58]

These laws highlight the commitment of the American people to protect individuals and employers from mandates or other requirements forcing them to violate their consciences and/or religious and moral beliefs, and demonstrate that the Government's

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[55] Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209 (2007).

[56] Many similar conscience provisions related to federal funding have been passed over the last 45 years. *See, e.g.*, 42 U.S.C. § 1395w-22(j)(3)(B) (1997); 42 U.S.C. § 300a-7(e) (1979); 42 U.S.C. § 300a-7(c)(2), (d) (1974); 42 U.S.C. § 300a-7(b), (c)(1) (1973); 48 C.F.R. § 1609.7001(c)(7) (1998); Pub. L. No. 108-25, 117 Stat. 711, at 733 (2003).

[57] *See* Pub. L. No. 108-7, 117 Stat. 11, 126-27 (2000).

[58] *See* Pub. L. No. 108-7, 117 Stat. 11, 472 (1999).

Mandate ignores the longstanding national commitment to protect the freedom of conscience.[59]

CONCLUSION

It is undisputed that a new human organism is created at fertilization. Being forced to pay for drugs that can end a human life after fertilization is forced participation in the act itself. Such a coercive policy runs contrary to the history, tradition, and jurisprudence of this Nation and violates the family businesses' freedom of conscience.

For the forgoing reasons, this Court should conclude that the Government's Mandate unconstitutionally denies the family businesses the religious freedom guaranteed under the Religious Freedom Restoration Act and the Free Exercise Clause of the First Amendment, and should affirm the decision of the United States Court of Appeals for the Tenth

[59] The Government's actions also run contrary to the laws and clear intent of the vast majority of states that protect the freedom of conscience. At least 47 states provide some degree of statutory protection to healthcare providers who conscientiously object to certain procedures. Some states – including Louisiana and Mississippi – extend this protection to public and/or private payers (*i.e.*, health insurers). *See Rights of Conscience Overview*, in DEFENDING LIFE 2013: DECONSTRUCTING ROE: ABORTION'S NEGATIVE IMPACT ON WOMEN (2013), http://www.aul.org/wp-content/uploads/2013/04/06-Freedom-of-Conscience.pdf.

Circuit and reverse the decision of the United States Court of Appeals for the Third Circuit.

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